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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,677	08/16/2001	Donald F. Weaver	NCI-006DV1	5945

959 7590 04/20/2006

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,677	WEAVER ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68,138,142 and 145-186 ~~is~~/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68,138,142 and 145-186 ~~is~~/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>111605 & 020906</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment filed on January 30, 2006.

Claims 68, 138, 142 and 145-186 are pending in this application.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are under new grounds:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 68, 138, 142, and 145 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 953,997. The instant claims read on the therapeutic use of the reference disclosed compound. The reference teaches a β -alanine compound, see the structural formula in page 1, and the corresponding therapeutic use of the compound. The reference teaches that the compound showed activity on neurological accident, specifically in a case of epilepsy, see page 3, lines 114-120.

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2. Claims 68, 138, 142, and 145 are rejected under 35 U.S.C. 102(b) as being anticipated by Bey et al., U.S. Patent No. 4,375,477. The instant claims read on the therapeutic use of the reference disclosed compound. The reference teaches a substituted β -alanine compound, see the structural formula I in col. 2, and the corresponding therapeutic use of the compound. The reference teaches that the compound is useful in the treatment of central nervous system disorders such as seizure disorders associated with epilepsy, see col. 3, lines 38-43.

Note: The instant claims recite “substituted β -amino anionic compound”, however, it is recited that “two-carbon spacer **may be** substituted with a substituent”, which does not set forth that it is required that the two-carbon spacer is substituted.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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1. Claims 68, 138, 142 and 145-186 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60-99 of copending Application No. 10/272,249. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims substantially overlap the reference claims. The reference claims are drawn to 'a method for inhibiting epileptogenesis comprising administering a compound of formula A or B' which formulae are structurally analogous to the active ingredient, i.e., substituted β -amino anionic compound of the instant claims. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the disorders embraced by the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that the compounds to have the same activity and therefore useful in treating the disorders taught in the reference. One of ordinary skill in the art would have been motivated to use the substituted β -amino anionic compound taught by the reference in the treatment of the specific disorders of the instant claims because such therapeutic method would have been suggested by the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 68, 138, 142, 145, and 151-162 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60-99 of copending Application No. 11/099,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims substantially overlap the reference claims. The reference claims are drawn to 'a method for inhibiting epileptogenesis

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comprising administering an anti-epileptogenic agent which is a β -heterocyclic- β -amino acid' which is structurally analogous to the active ingredient, i.e., substituted β -amino anionic compound of the instant claims. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the disorders embraced by the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that the compounds to have the same activity and therefore useful in treating the disorders taught in the reference. One of ordinary skill in the art would have been motivated to use the substituted β -amino anionic compound taught by the reference in the treatment of the specific disorders of the instant claims because such therapeutic method would have been suggested by the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Receipt is acknowledged of the Information Disclosure Statements filed on November 16, 2005 and February 9, 2006 and copies are enclosed herewith.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deepak Rao
Primary Examiner
Art Unit 1624

April 17, 2006